"pushing" or infusing the drugs into the patient, consulting with the patient providing family and grief counseling, managing patient side effects, and maintaining proper inventories. Particularly since some of the common patent-protected cancer agents cost more than $10,000, inventory costs were often considerable.[132]

94. In any case, after receiving public comments, in 1992 HCFA adopted a uniform national payment system based on 100% of AWP, but also authorized surveys that were to report on physicians' Part B actual acquisition costs, as well as related office practice treatment service costs. Other proposals for changing the reimbursement basis for Medicare Part B drugs were also considered during the 1990s. Congress did not adopt a Clinton Administration proposal that Medicare Part B change payment from one based on AWP to one based on actual acquisition costs, nor did it adopt another proposal that Medicare lower the payment rate to 83% of AWP.[133]

95. In 1997, after considerable debate, Congress passed the Balanced Budget Act of 1997, in the process lowering Medicare payments for single source drugs and biologics to 95% of AWP. For drugs for which there are two or more competing brand name products (referred to as multisource drugs) or generic equivalents available, Medicare reimbursed at 95% of the lower of (a) the median AWP of all generic forms of the drug, or (b) the lowest brand-name product AWP.[134]

96. Medicare's reimbursement for physician-administered drugs has continued to be controversial. Under terms of the Medicare Modernization Act of 2003, beginning in January 2005, Medicare Part B drugs will be reimbursed at 106% of ASP (actual average manufacturers'

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[132] American Society of Clinical Oncologists [2001], *supra*, pp. 2-9.
[133] American Society of Clinical Oncologists [2001], *supra*, pp. 8-9.
[134] MedPAC [2003], supra, pp. 153-154.

sales price),[135] although during the transition year of 2004 the basis for drug reimbursement was set at 85% of AWP.[136] However, there appears to be some confusion regarding how biotech products will be reimbursed, and how Medicare will calculate ASP may differ from how Medicaid calculates AMP.[137] What is apparently clear is that in recognition of the AWP-related cross-subsidy provided physicians administering Medicare Part B drugs, Medicare is also increasing physician service fees; in the case of inhalation drugs delivered by nebulizers, for example, the dispensing fee has increased from $5 to $57.[138] It is my understanding that MedPAC and/or OIG is to report on reimbursements as they affect oncologists and other specialties in the near future, and on the way in which ASP is calculated.[139]

97. In summary, with Medicare Part B physician-administered drugs there has been a long simmering controversy regarding the extent to which AWP-based reimbursements adequately compensated physicians for the costs of services they provided in administering the drug treatment. It is instructive to compare the bundling of payor payments for generic self-

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[135] "New MMA methodology for drug prices is a big change for many payers", available online at http://www.managedhealthcareexecutive.com/mhe/article/articleDetail.jsp?id=136812, last accessed 2/6/2005.

[136] *Declaration of Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification,* September 3, 2004, Attachment D, p. 5. Also see MMA – Drugs Paid by Average Selling Price Beginning January 1, 2005, available at www.cms.hhs.gov/medlearn/matters/mmarticles/2004/MM3232.pdf, last accessed 2/6/05.

[137] An article reprinted from the January 2004 issue of Specialty Pharmacy News states: "For 2004, single-source biotech products administered in an outpatient hospital setting will be reimbursed at 88% of Average Wholesale Price (AWP) in 2004, and at 83% of AWP in 2005. Innovator multiple—source drugs will be reimbursed at a minimum level of 68% of AWP in both 2004 and 2005. And non-innovator multiple source drugs will be reimbursed at 46% of AWP in both 2004 and 2005. For all these calculations, the AWP used is as of May 1, 2003. In 2006 the form law calls for a new payment method to be developed to more accurately reflect the costs of acquiring, handling and storing drugs and biologicals. The new reimbursement system will be based on a market-based reimbursement rate known as Average Sales Price (ASP). ASP will be calculated from data provided by the manufacturers for drugs and biologicals administered in hospital outpatient settings." Available online at http://www.aishealth.com/DrugCosts/specialty/spnMedicareReform.html, last accessed December 28, 2004. The AMP is defined in a DHHS Rebate Agreement document, available at www.cms.hhs.gov/medicaid/drugs/rebate.pdf, last accessed 2/6/05. Details on the calculation of ASP for Medicare are found in the King & Spaulding document, "Drug Pricing and Reporting: The Next Compliance Challenge", available at www.kslaw.com/library/pdf/drugconferenceslides.pdf, , last accessed 2/6/05.

[138] An Orientation to the Acquisition of and Reimbursement for Prescription Drugs, Tutorial Submission of the Track One Defendants before Judge Patti B. Saris, by Gregory K. Bell, Ph.D. and Fiona Scott Morton, Ph.D., December 7, 2004, p. 36.

[139] United States Department of Health and Human Services' Office of Inspector General Issues "Work Plan Fiscal Year 2005 , dated 1/11/3005, available online at http://www.agg.com/Contents/PublicationDetail.aspx?ID=1205, last accessed 2/7/05.

administered drugs to the bundle of payor payments to medical/physician providers for dispensing and administering drugs. Although the phenomenon of bundling ingredient cost and dispensing fee reimbursements to pharmacies to incentivize them to dispense generic drugs has apparently enabled both pharmacy and payer to benefit, for self-administered Medicare Part B drugs the bundling of ingredient cost and administration services into an AWP-based reimbursement has raised considerably more difficult and challenging issues, issues on which payer and provider are finding it more difficult to reach agreement. While I will not reproduce the histories here, it is also quite clear that knowledgeable observers understood that physicians were able to purchase many of the Medicare Part B outpatient drugs at acquisition costs considerably less than AWP.[140,141]

98. Physicians administer drugs not only to Medicare Part B patients, but also to non-Medicare patients, such as under age 65 individuals requiring nebulizers, or under-65 patients diagnosed with and treated for cancer. Commercial carriers typically negotiate reimbursements/payments with physician practices or other provider networks when such physician-administered drug services are provided. The record in this case is unsettled to date as to whether those payments to physicians for physician-administered drugs and related services are based predominantly on AWP (as has been argued by Plaintiffs' experts Raymond Hartman[142] and Professor Meredith Rosenthal[143]) or instead are negotiated as part of the overall

[140] For a review of some of the public studies, see MedPAC [2003], *supra*. Also see Attachment B to this report.
[141] Earlier in this report I quoted Professor Kolassa's [1994a] description of the perverse incentives facing any given generic manufacturer to attempt unilaterally to set its ex-factory prices close to its AWPs. While that description written quite some time ago, Plaintiffs have provided evidence that this incentive structure persists to the present today – at least in the context of physician-administered drugs; see, for example, the Dey Complaint (Dey is a generic specialty drug manufacturer) cited in *Plaintiffs' Reply to Schering-Plough Group's Individual Memorandum in Opposition to Class Certification*, December 17, 2004, pp. 9-10.
[142] *Declaration of Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification*, September 3, 2004, Attachment D, p. 10, citing the Dyckman & Associates 2002 report, which reported AWP reimbursement rates from commercial carriers varying between 85% and 115% of AWP.

physician fee schedule involving both drugs and services, based on "charges" rather than on costs (as has been argued by Defendants' Expert Steven J. Young[144]). While I note the controversy here, I will not comment on it further at this time.

99. It is important to note, however, that very important differences exist between self-administered and physician-administered drugs involving their distribution and management. One of the more important differences concerns distribution logistics. Many physician-administered drugs are sold by manufacturers directly to physicians or to hospitals' outpatient departments; group purchasing organizations ("GPOs") often act as intermediaries between manufacturers and physicians/hospitals, although typically GPOs, like non-mail order PBMs, do not actually take title to the drugs.[145] Providers receive reimbursement for the drug as well as compensation for the services of administering the drug. Less frequent is the situation when specialty and retail pharmacies distribute the products directly to patients. In some cases pharmacies may provide the drug to physicians, but then receive reimbursement directly from the health plan/insurer, thereby eliminating the physician reselling transaction.[146]

100. A second major difference between self-administered and physician-administered drugs involves the fact that while PBMs have become crucial agents in impersonally and efficiently electronically adjudicating billions of prescriptions for self-administered brand and generic drugs, thereby serving as a behind-the-scenes invaluable intermediaries, the rapidly

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[143] Written tutorial of Meredith Rosenthal, Ph.D., before Judge Patti B. Saris, December 6, 2004, p. 10, citing the same Dyckman & Associates 2002 report, quoting it as saying "that most plans use a pricing formula that is in the range of 90% to 100% AWP, with the average at 98% of AWP."

[144] *Sur-Reply of Steven J. Young in Opposition to the Plaintiff's Motion for Class Certification*, January 20, 2005, pp. 6-21, and accompanying appendices.

[145] *Declaration of Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification*, September 3, 2004, Attachment C, p. 5; Stephen W. Schondelmeyer and Marian V. Wrobel, *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices*, Introduction, Final Report, Contract #500-00-0049, Task Order 1, Cambridge, MA: Abt Associates Inc., August 30, 2004, pp. 10-11.

[146] *Declaration of Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification*, September 3, 2004, Attachment C, p. 5.

growing specialty pharmacy intermediaries have been characterized instead as being "high cost and high touch", meaning that they provide specialized delivery and administration services on an ongoing basis, typically more individualized than that involving self-administered drugs.[147] Consider several examples.

101. While the combined specialty pharmacy – PBM firm Advance PCS reports that patients with chronic diseases requiring specialty drugs comprise 1% to 5% of a typical health plan's population, these patients nonetheless accounted for 25% to 50% of the plan's total medical costs. For example, a patient requiring recombinant hemophilia factor on average has a drug therapy cost of $150,000 per patient year, but may cost up to several million dollars. Part of the challenge of managing such a patient is that with hemophilia, patient's required usage is typically difficult to predict, but when needed, the need is acute, so that managing inventory becomes a critical cost factor.[148]

102. A November 2001 article in the trade journal *Employee Benefit Plan Review* highlighted the rapid growth of specialty pharmaceutical sales, and noted that increasingly PBMs were developing alliances with or starting their own specialty pharmacies. The article noted recent alliances between Merck-Medco Managed Care and CVS' ProCare, AdvancePCS alliance with Priority Healthcare JV and its acquisition of TheraCon, and Express Scripts' founding of Specialty Distributions in 1998.[149]

103. In short, while self-administered drugs are managed electronically and impersonally via PBMs, for physician-administered drugs, the management is more

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[147] AIS [2003], p. 2.
[148] "AdvancePCS Views Its Specialty Rx as Complementary to Caremark's Approach", reprinted from the January 2004 issue of Specialty Pharmacy News, pp 2-3. Available online at http://www.aishealth.com/DrugCosts/specialty/SPNAdvancePCSComplementCaremark.html, last accessed 12/29/2004.
[149] "Specialty Drugs, Pharmacies: A Growing Trend", in *Employee Benefit Plan Review*, November 2001, 56(5), pp. 22-24.

individualized, and is increasingly done so by specialty pharmacies (who are increasingly aligning themselves with PBMs). I note in passing that since many of the physician-administered drugs are single-source, and the only product in their therapeutic class, to date rebates have been relatively rare. Apparently the extent to which manufacturers have been willing to provide rebates to specialty pharmacies has been increasing, with rebates ranging from 6% to 15% of WAC.[150] With rebates being relatively rare, the principal way in which plans can save costs is to manage the specialty pharmaceuticals closely.[151]

104. A third major difference between self-administered and physician-administered drugs concerns the insurance provisions under which benefits are provided. By definition, virtually all of the self-administered drugs are purchased and administered on the plan's prescription drug benefit, most of them involving a PBM. In contrast, approximately 70% of specialty drugs are purchased and administered on the medical side of the benefit.[152]

105. Reporting on an April 4, 2002 roundtable discussion hosted by Ancillary Care Management ("ACM"), AIS Health stated that "ACM claims that approximately two-thirds of the time, injectable drugs are covered under the major medical benefit, whereas only one-third of the time they are covered under the pharmacy benefit, and it may often be up to the health plan to decide where the benefit falls."[153] The article then went on to provide an example:

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[150] "Effective Plan Design Helps Keystone Get Specialty Rx Rebates", reprinted from the January 12, 2004 issue of Managed Care Week, p. 1. Available online at http://www.aishealth.com/DrugCosts/specialty/MCWKeystoneRxRebates.html, last accessed 12/28/2004.
[151] Atlantic Information Services, Inc., *Specialty Pharmacy: Stakeholders, Strategies and Markets*, Edited by Susan Namovicz-Peat, 2003, pp. 32-33. Hereafter I call this document AIS [2003].
[152] Various estimates of this medical vs. drug split of benefits for specialty drugs are given in AIS [2003], p. 84. Also see "Tenn. Blues Choose Three Specialty Rx Vendors, Create Product List", reprinted from the January 2004 issue of Specialty Pharmacy News, p. 3. Available online at http://www.aishealth.com/DrugCosts/specialty/spnTennBlues.html, last accessed 12/29/2004.
[153] [153] "Defining Specialty Pharmacy: Services, Market and Players," p. 5. Available online at http://www.findarticles.com/p/articles/mi_mONK/is_7_3/ai_89237271/print, last accessed 12/28/2004.

> "For instance, depending on the type of injectable, or whether the patient is enrolled in PPO- or HMO-based plans, Aetna members may receive the drug under either the pharmacy or medical benefit. In Aetna PPO-based plans, all covered self-injectable drugs are available under the standard pharmacy benefit. According to BioScrip, 40% of its managed injectables will be covered under the pharmacy benefit. As a result, there is no standard benefit management at this time for specialty pharmaceuticals, and in the future PBMs may have to establish consistent guidelines of how to manage the drug benefit."[154]

An *Employee Benefit Plan Review* news article predicted that because of the increasing awareness of specialty drugs by PBMs, as well as the growing alliances between specialty pharmacies and PBMs, a shift from the medical to the pharmacy benefit may accelerate, exposing perhaps the very high cost of the biotechnology drugs.[155]

106. Converting specialty products from the medical benefit to the pharmacy benefit is not always easy. RESTAT, a PBM, reports that while it was relatively easy to transfer new payments from medical to pharmacy benefits, that was not always so with patients who had an extended history of receiving the product under the medical benefit, for such patients often had cemented their relationship with their provider, and were hesitant to switch from physician-administered to self-administered. By manipulating the copay differential between medical and pharmacy benefits, in particular by lowering the patient copayment as the patient switched from physician to self-administered, the health plan was however able to make sure the product was purchased from the preferred specialty provider, rather than allowing the physician to purchase the product from a supplier of his or her own choosing.[156]

107. A fourth major difference between self-administered and physician-administered drugs concerns the very different roles played by the prescribing physician. While for self-

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[154] "Defining Specialty Pharmacy: Services, Market and Players," p. 5. Available online at http://www.findarticles.com/p/articles/mi_mONK/is_7_3/ai_89237271/print, last accessed 12/28/2004.
[155] "Specialty Drugs, Pharmacies: A Growing Trend", in *Employee Benefit Plan Review*, November 2001, 56(5), pp. 22-24.
[156] "Accelerating Pipeline Said to Drive Need for Payer SP Strategies", reprinted from the May 2004 issue of Specialty Pharmacy Times, pp. 2-3. Available online at http://www.aishealth.com/DrugCosts/specialty/SPNAcceleratingDriveNeed.html, last accessed 12/29/2004.

administered drugs typically the prescribing physician does not dispense the drug (instead, the pharmacy does), for physician-administered drugs the prescriber is typically also the dispenser, implying that a potential conflict exists between physicians attempting to provide cost-effective and appropriate treatments for their patients, and physicians acting as dispensers of drugs receiving the benefits of any differential between the drug's acquisition costs, and reimbursement received from Medicare Part B or a commercial payor. This creates a variety of problems. As one industry trade reference source states:

> "The management of injectable drug costs represents a challenge to managed care organizations, and the main reason is that physicians often are the providers for these medications. Further, these physicians are often specialists who have, over time, made substantial profits for the provision of these medications.
>
> And, unlike pharmacies with oral prescription drugs, these specialists represent a much greater challenge to contract with or to find alternatives for patient care. For example, it is easier to negotiate pharmacy network rates with chain and independent pharmacies for oral medications. This is because competition among prescription drugs is so fierce, and the abundance of pharmacies in the area can 'soften' the market prices.
>
> Specialist physicians, on the other hand, are less abundant and have deeper personal relationships with patients. Therefore, to negotiate a lower reimbursement or otherwise sever the patient-physician bond adds an extra dimension to the challenge of providing injectable drugs.
>
> In addition, these specialists typically contract with many different health plans. As such, no one plan represents a majority of business for that physician, so plans hold minimal leverage to demand special rates. In response to these challenges, some health plans have elected to use specialty drug companies to provide these drugs to physicians rather than paying the physicians for the provision of these drugs to patients."[157]

In the now highly visible scandals involving Lupron and Zoladex, the profit "spread" was gamed and marketed by manufacturers using terms such as "return to practice".[158] Without digressing into details of that case, here I simply want to point out that managed care organizations trying to

[157] AIS [2003], *supra*, pp. 72-73.
[158] See Judge Stearns statements in United States District Court, District of Massachusetts, MDL No. 1430, Master File No. 01-CV-10861-RGS, *In Re: Lupron Marketing and Sales Practices Litigation, Memorandum and Order on Defendants' Motion to Dismiss Corrected Consolidated Amended Class Action Complaint and Second Amended Consolidated Complaint.*

aggressively contain costs and ensure that their beneficiaries are obtaining cost-effective treatments face a tradeoff that is very different in their dealings with PBMs and self-administered drugs.

108. Specifically, with physician-administered drugs, health plans/insurers risk losing valued physicians from their specialty networks (with all the implications that has for the competitiveness and relative attractiveness of the plans they offer employers) if they move patients from medical to pharmacy benefits and contract through specialty pharmaceuticals or PBMs for purchasing these drugs, instead of letting physicians capture the benefits of purchasing the drugs themselves and implicitly reselling them to payors. As a result, payors may not be quite as aggressive in obtaining cost information about these drugs, as they would be were they dealing with pharmacy-dispensed drugs. I discuss this further in Section V below.

109. Interestingly, the specialty pharmacy literature provides considerable discussion of this conflict facing managed care organizations. One article, for example, noted that for a rheumatoid arthritis drug, some physicians in certain geographic regions of the US were reluctant to give up profits from self-dispensing the drug. In some areas of the US, there is apparently a shortage of rheumatologists, and in those areas the rheumatologists may have as much leverage as oncologists in contracting with specialty pharmacy vendors and health plans.[159] Other industry trade articles provided managed care organizations with advice and examples of how they had worked with payors to develop cost containment strategies and yet simultaneously not lose valuable specialist physicians from their networks.[160]

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[159] "Accelerating Pipeline Said to Drive Need for Payer SP Strategies", reprinted from the May 2004 issue of Specialty Pharmacy Times, p. 3. Available online at http://www.aishealth.com/DrugCosts/specialty/SPNAcceleratingDriveNeed.html, last accessed 12/29/2004.

[160] Illuminating articles in this context include Chris Nee, "Essentials for Cost-Effective, Win-Win Injectables Management", reprinted from the July 11, 2003 issue of Drug Cost Management Report, 4 pp. Available online at http://www.aishealth.com/DrugCosts/DCMRWinWin.html, last accessed 12/29/04; also see "Highmark's New 'Payer-Friendly' SP Firm Forecasts '04 Profits, Growth", reprinted from the January 2004 issue of Specialty

110. These important differences between the distribution and management of self-administered vs. physician-administered drugs have significant implications for information flows, competition and price transparency. In Section IV that follows immediately, I discuss competition, information flows and price transparency in the context of PBMs and self-administered drugs. I defer to Section V an associated discussion of information, price transparency and competition in the context of self-administered drugs.

IV. PBM COMPETITION AND PRICE TRANSPARENCY: SELF-ADMINISTERED DRUGS

111. In Section III, Subsections A, B and C I have noted that information concerning the extent of the spread between AWP and WAC, or AWP and ASP, for self-administered drugs has been widely although not universally diffused among manufacturers, retailers, payors, policy makers and PBMs. I now examine information and price transparency issues particularly associated with PBMs in their role as intermediaries managing purchases of self-administered drugs.

112. Plaintiffs' Expert Dr. Raymond Hartman argues that the pharmaceutical industry is plagued by "the lack of pricing transparency",[161] and that this is particularly true for PBMs who "possess strategic information advantages as a result of the central and critical position they occupy". He then asserts: "*The importance of control of this information cannot be understated, given the overall lack of pricing transparency in this industry.*" [162]

Pharmacy News, 5 pp. Available online at http://www.aishealth.com/DrugCosts/specialty/spnHighmark.html, last accessed 12/29/04.

[161] *Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification*, 16 December 2004, p. 4.

[162] *Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification*, 3 September 2004, Attachment C, p. 11. Italics in original.

113. Over the years, PBMs have been the focus of considerable scrutiny from the U.S. Department of Justice ("DOJ") and the Federal Trade Commission ("FTC"), from states' Attorneys General, and from other private players in the health care system. In these contexts, it is useful to distinguish three situations in which informational asymmetries could potentially harm competition, and the actions that have been taken over the last decade by governmental and private sector agents regarding information flows and competition: (i) drug manufacturers acquiring a PBM and thereby becoming vertically integrated; (ii) large PBMs, not owned by drug manufacturers, merging with each other; and (iii) large PBMs, not owned by drug manufacturers, vertically integrating with mail order pharmaceutical distributors. I now consider each of these, in turn, all in the context of self-administered drugs.

A. Information with Vertically Integrated Drug Manufacturers and PBMs

114. In 1993, Merck & Co. acquired Medco Containment Services, thereby becoming the first vertically integrated drug manufacturer – PBM; Merck named its subsidiary Merck-Medco Managed Care, LLC. About a year later, SmithKline Beecham acquired Diversified Pharmaceutical Services ("DPS"). Soon thereafter, Eli Lilly and Company acquired PCS, another PBM, from the McKesson Corporation. Other manufacturers entered into alliances with PBMs, such as Pfizer with ValueHealth.[163]

115. These mergers attracted the attention of the Federal Trade Commission ("FTC"), and over the years have resulted in a number of investigations. FTC activities up through 1999 are discussed by FTC economist Roy Levy, who focuses in particular on how "revolutionary developments in information technology" affected PBMs' relationships with not only

[163] *HCFA Study of Pharmaceutical Benefit Management*, Contract No. 500-97-0399/0097, Federal Project Officer, Dr. Peri Iz, June 2001, p. 23. Online at www.cms.gov/researchers/reports/2001/cms.pdf, accessed January 14, 2005.

manufacturers, but also with wholesalers, retailers, physicians and other providers, and payers.[164] While the FTC recognized that PBMs facilitated price competition by, for example, using formularies and information technology that enabled real-time substitution among alternative prescription drug treatments, the FTC also worried publicly about the PBMs' combination of access to competitor information and information that might facilitate information exchanges among drug companies, thereby enhancing the likelihood of price coordination that could harm consumers.[165]

116. In 1995 the FTC challenged aspects of the vertical acquisition of PCS Health Systems by Eli Lilly & Co., obtaining a consent decree, and establishing a "firewall" between Lilly and PCS. At that time the FTC also pledged to monitor the PBM industry carefully, and cautioned that it might take future action if it concluded there were signs of anticompetitive conduct in the industry. In August 1998 the FTC announced an agreement with Merck & Co. and its subsidiary, Merck-Medco Managed Care, resolving FTC antitrust concerns, again obtaining a consent agreement establishing a "firewall" between drug manufacturer and PBM. In both cases, the drug manufacturer agreed to maintain an open formulary that included drugs selected and approved by an independent Pharmacy and Therapeutics ("P&T") Committee.[166] Apparently, upon acquiring the PBM Diversified Pharmaceutical Services, SmithKline Beecham voluntarily agreed to similar provisions, including construction of a similar firewall.[167]

117. Whether for reasons due to potential PBM clients being skeptical and cautious, or because of successful FTC regulatory intervention, or both, the merged PBM-manufacturer

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[164] Roy Levy, *The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change*, Washington DC: Bureau of Economics Staff Report, Federal Trade Commission, March 1999, p. ix.
[165] Levy [1999], *supra*, p. 100, 140.
[166] Press Release, "Merck Settles FTC Charges that Its Acquisition of Medco Could Cause Higher Prices and Reduced Quality for Prescription Drugs", August 27, 1998. Online at http://www.ftc.gov/opa/1998/08/merck.htm .
[167] Levy [1999], *supra*, p. 102.

entities have not been sustainable, and instead several have given rise to spin-off merged retailer-PBM entities.

118. In 1999 SmithKline Beecham sold DPS to an existing PBM, Express Scripts, and Lilly sold PCS to chain drug retailer Rite Aid (who one year later sold PCS to PBM Advance Paradigm, creating AdvancePCS). Both Lilly and SmithKline Beecham divested their PBMs for significantly less than they were acquired. Lilly, for example, reduced the book value of its PCS Health System PBM by $2.4 billion, more than 50% of its initial $4.1 billion purchase price, prior to selling it to Rite Aid. Citing press accounts, an FTC report suggests that Lilly may have been "mistaken about the ability of PCS to expand its drug sales" and that other drug manufacturer acquisitions of PBMs "led to changes in prescription drug sales that fell short of expectations".[168] The FTC then comments on this vertical integration experience as follows:

> "The reduction in Lilly's book value, as well as its recent sale of PCS to Rite Aid Corporation, equally calls into question whether this vertical merger led to higher prices or profits from anticompetitive foreclosure. This may simply reflect the success of regulatory intervention. {Footnote Not Reproduced}. Alternatively, it may mean that exclusionary practices, such as efforts by vertically integrated drug companies to limit competitor access to the drug formularies of downstream PBM affiliates, {Footnote Not Reproduced}, were not successful in achieving anticompetitive foreclosure in this case {Footnote Not Reproduced}. In short, Lilly's decision to mark down the book value of PCS offers little support for either an efficiency or an anticompetitive interpretation of that transaction.[169]

119. Instead of vertical integrations involving drug manufacturers and PBMs, we now observe retailer-PBM vertical integrations. Chain retailer Eckerd now operates Eckerd Health Services, its PBM, as does CVS with PharmaCare, and Walgreens with Walgreens Health

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[168] Roy Levy, *The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change*, Bureau of Economic Analysis, Federal Trade Commission, March 1999, p. 126.
[169] Levy, *supra*, p. 127.

Initiative. Chain grocer Kroger has a PBM named Kroger Managed Prescription Drug Program.[170]

120. Finally, in 2002 Merck & Co. announced its intention to spin-off its PBM subsidiary, and on August 12, 2003, Merck announced the completion of its spin-off of Medco Health Solutions, Inc.[171] To the best of my knowledge, Merck & Co., Inc. is not a defendant in this case, although Medco is.

121. Regarding these mergers between manufacturers and PBMs, Plaintiffs' Expert Dr. Raymond Hartman acknowledges " this consolidation did not prove successful, and by 2003 the relevant manufacturers had divested their PBMs."[172]

B. Information with Horizontally Integrated Independent PBMs

122. PBMs have become central players in constructing, managing, and delivering drug benefits to insured populations. From relatively humble beginnings as regional electronic managers of transactions, PBMs have now evolved into full service, web-enabled, nation-wide pharmaceutical services organizations.

123. As shown in Exhibit A below, over the years the set of PBM service offering has expanded considerably, and these offerings increasingly place the PBM industry in a central position electronically linking pharmaceutical manufacturers, pharmacies, payors, physicians and patients. According to Defendant's Expert Steven J. Young, in 1994 58% of health plans contracted with PBMs, but by 1999 this proportion had increased to 90%. Moreover, "Today approximately 95% of all patients with drug coverage receive benefits through a PBM that has

[170] Banc of America Securities [2002], *supra*, pp. 15-16; HCFA Study of Pharmaceutical Benefit Management [2001], *supra*, p. 24.
[171] Press Release, "Merck & Co., Inc. Completes Spin-Off Of Medco Health Solutions, Inc.", online at http://www.merck.com/newsroom/press_releases/corporate/2003_0820.html, accessed 20 January 2005.
[172] Hartman [2004], *supra*, Attachment C, p. 9.

contracted with a commercial or government-sponsored plan."[173] PBMs have become ubiquitous actors in the management of purchases of self-administered drugs.

Exhibit A

Growth of PBM Service Offering

				Medicare Drug Plan
				Internet Content
				Specialty Pharmacy
			Disease Management	Disease Management
		Prior Approval	Prior Approval	Prior Approval
		Pharmacy Networks	Pharmacy Networks	Pharmacy Networks
		Drug Reviews	Drug Reviews	Drug Reviews
	Co-Pays	Co-Pays	Co-Pays	Co-Pays
	Mail Order	Mail Order	Mail Order	Mail Order
Claims Processing	Claims Processing	Claims Processing	Claims Processing	Claims Processing
1970 s	**1980 s**	**Early 1990 s**	**Late 1990 s**	**Future State**

Source: Goldman Sachs Global Equity Research, Healthcare: Supply Chain – Pharmacy Benefit Managers, United States, October 16, 2003, Exhibit 2, p. 4.

124. A Goldman Sachs Global Equity Research industry overview of today's PBM industry describes its central role as follows:

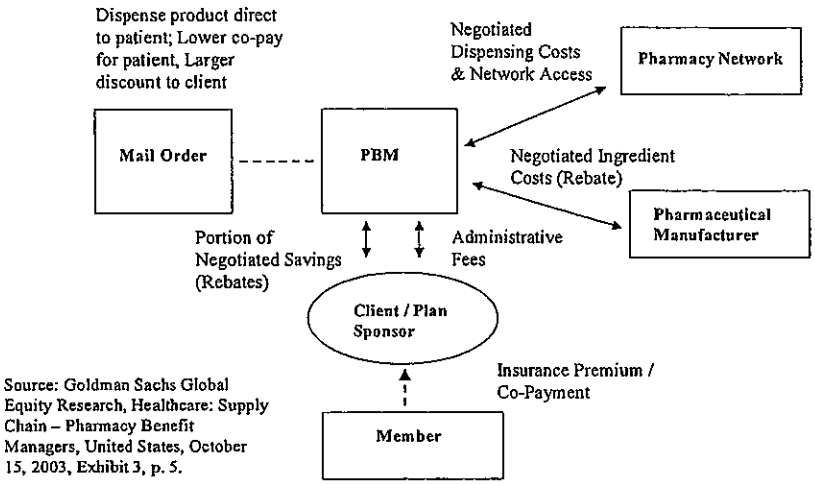
> "The demand of large populations (employee or managed care) for ubiquitous, flexibility, standardization and national access to pharmaceutical benefits drives the scale characteristics of pharmaceutical benefit managers. Linking hundreds of manufactures, thousands of products, and tens-of-thousands of retail dispensing points, demands sophisticated process management capabilities (think Automated Teller Machines – ATMs for drugs) with real-time access to patient billing and clinical data.

The same Goldman Sachs Global Equity Research overview graphically depicts the critical central actor role played by PBMs; below I reproduce their graphic as Exhibit B.

[173] Declaration of Steven J. Young in Opposition to the Plaintiff's Motion for Class Certification, October 25, 2004, p. 37.

Exhibit B

PBM Industry Flow Chart



Source: Goldman Sachs Global Equity Research, Healthcare: Supply Chain – Pharmacy Benefit Managers, United States, October 15, 2003, Exhibit 3, p. 5.

125. The central role played by PBMs makes it particularly important that the industry be competitive, and that information flows be sufficient to facilitate workable competition benefiting consumers. In part because of debate concerning the appropriate role of PBMs in helping to administer the new Medicare Part D drug benefits in the US, and because of antitrust concerns in the wake of a proposed merger involving two large PBMs, much attention has recently been focused on the PBM industry. In the paragraphs that follow I discuss the PBM industry structure, the extent of price and rebate transparency, and recent as well as known forthcoming FTC actions involving PBMs.

B. 1. Documentation of Continuing Diverse PBM Ownership

126. There has been and continues to be considerable diversity in the ownership structure of PBMs. This has important implications regarding the extent to which "secret" practices can be carried out on a sustained basis without being uncovered. First I document this

diverse ownership for the most recent time period (2002 to the present), then for the first quarter of 1999, and finally for 1995/1996.

127. Over the past few years (say, 2002 to the present) some PBMs have been essentially stand-alone entities; these include Medco Health (since the 2003 dissolution of Merck-Medco Managed Care), AdvancePCS, Express Scripts, Inc. and Caremark Rx, Inc.[174] A substantial number of PBMs are owned by managed care organizations; these include WellPoint Pharmacy Management (owned by WellPoint Health Networks), Aetna Pharmacy Management (Aetna), Prime Therapeutics (Blue Cross Blue Shield of Minnesota, Nebraska, North Dakota and Wyoming), Prescription Solutions (PacifiCare Health Systems), Anthem Prescription Management (Anthem), CIGNA Pharmacy Services (CIGNA HealthCare), Pharma-Link (Blue Cross Blue Shield of Kansas City) and First Health (First Health).[175] Still other PBMs are owned by retail pharmacy/grocery chains; these include Eckerd Health Services (owned by Eckerd), PharmaCare Management Services (CVS Pharmacy), RxAmerica (Longs Drug Stores Corporation, joint with Albertson's), Walgreens Health Initiative (Walgreens), and Kroger Managed Prescription Drug Program.[176] It appears that even some wholesalers own PBMs, e.g.,

[174] I note that recently Advance PCS was acquired by Caremark Rx. The proposed acquisition was announced on September 2, 2003. See Goldman Sachs Global Equity Research, *Healthcare: Supply Chain – Pharmacy Benefit Managers, United States,* October 16, 2003, p. 56, Exhibit 59, and p. 57. Apparently this merger was consummated in March 2004. See *Declaration of Stephen W. Schondelmeyer in Support of Plaintiffs' Motion for Class Certification*, September 2, 2004, p. 10, footnote 2.

[175] Credit Suisse First Boston Equity Research, *Down Low, Volume II – Quarterly PBM Thoughts*, February 9, 2004, Exhibit 29, p. 33. Also see Goldman Sachs Global Equity Research, *Healthcare: Supply Chain – Pharmacy Benefit Managers, United States,* October 16, 2003, pp. 10-12.

[176] Banc of America Securities, Equity Research United States, *Pharmacy Benefit Managers: Keeping a Lid on Drug Costs*", Health Care Technology and Distribution Industry Overview, February 2002, p. 16. Goldman Sachs Global Equity Research, *Healthcare: Supply Chain – Pharmacy Benefit Managers, United States,* October 16, 2003, pp. 10-12.

Managed Pharmacy Benefits, by wholesaler Cardinal Health,[177] and RESTAT, owned by wholesaler F. Dohmen Company.[178]

128. A January 2000 report commissioned by the Henry J. Kaiser Family Foundation, and conducted by Mathematica Policy Research Inc., identifies the 20 largest PBMs in the first quarter of 1999, ranked by the number of retail pharmacy prescriptions managed.[179] Based on information available from the PBMs websites, I was able to determine their ownership type as of the first quarter of 1999. The results of this search are given in Attachment D. As is seen there, as of 1999Q1, seven of the top 20 PBMs were independent (Express Scripts/Value Rx, Advance Paradigm, Caremark Prescription Services, Prescription Solutions, National Prescription Administrators, MedImpact/MedCare, and Prime Therapeutics), five of the top 20 were owned by managed care/insurer organizations (Aetna Pharmacy Management, Wellpoint Pharmacy Management,[180] RxPrime, Prudential Pharmacy Management, and Proserve), five of the top 20 were owned by retailers (PCS Health System, ProVantage, Eagle Managed Care, RxAmerica, and PharmaCare Network), two were owned by pharmaceutical manufacturers (Merck Medco Managed Care, and Diversified Pharmaceutical Services, although during 1999 DPS was in transition to being acquired by independent PBM Express Scripts Inc.), and one was owned by a wholesaler (RESTAT).

129. I note in passing that this Kaiser Family Foundation report characterizes the PBM industry in 1999 as follows:

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[177] Banc of America Securities, Equity Research United States, *Pharmacy Benefit Managers: Keeping a Lid o n Drug Costs*", Health Care Technology and Distribution Industry Overview, February 2002, Figure 10, p. 18.
[178] See Attachment D to this report, indicating that in 1999, RESTAT was ranked the 20th largest wholesaler.
[179] Henry J. Kaiser Family Foundation, *The Role of PBMs in Managing Drug Costs: Implications for a Medicare Drug Benefit*, Prepared by Mathematica Policy Research, Inc., January 2000, Table 1, p. 8. Available online at www.pharmacy.ca.gov/publications/pbm_kff_role.pdf, last accessed 1/28/05.
[180] Although I was not able to confirm this, I believe it to be the case that Wellpoint, the owner of Proserve, is affiliated with the managed care firm Wellpoint.

> "Our review of the literature indicated that the PBM industry is highly competitive, and this point was also emphasized by those we interviewed. Competition is particularly keen on the fees for basic services that PBMs provide, such as claims processing."[181]

130. Ownership diversity going back to earlier times can also be documented. A study commissioned by the Health Care Financing Administration and published in 1996 depicts this diversity at a point in the mid-1990s. Of 107 PBMs identified by the University of Wisconsin researchers from industry and insurance directories, 89 yielded sufficient information by which they could be characterized, including ownership typology, lives covered, and services offered. Table 1, below, reproduces data from that study concerning ownership and coverage as of 1995/1996. The study authors note that many PBMs reported their origin as being a managed care organization (mco), a retail pharmacy, or a PBM (uniting claims processing and related services). As of 1995/1996, PBMs owned by retailers covered 7.6% of lives, independent PBMs covered 20.6% of lives, together managed care organizations, home care and insurance companies covered 24.7% of lives, while drug manufacturers covered 35.8% of lives, and wholesalers 1.4%. The study authors also comment that the PBM industry was dynamic, and that new entrants, exits, mergers, and name changes made the industry a "moving target".[182] What was true in 1995/1996 appears still to be the case today.

131. In addition to ownership diversity, there has been heterogeneity in the extent to which PBMs engage in mail order operations, the proportion of covered lives receiving benefits via mail order, the range of PBM services offered (see Exhibit A above), and whether service was provided on a regional vs. national basis.[183] The HCFA – University of Wisconsin study

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[181] The Henry J. Kaiser Family Foundation [2000], supra, p. 41. The report goes on to remark, "That said, the industry is dominated by a few large firms that could have an advantage in the bidding process." Ibid.
[182] HCFA Master Contract HCFA-95-023/PK, *Assessment of the Impact of Pharmacy Benefit Managers*, HCFA Master Contract HCFA-95-023/PK, University of Wisconsin-Madison, Center for Health Systems Research and Analysis; 30 September 1996. U.S. Department of Commerce, National Technical Information Service, pp. 22-32.
[183] See, for example, the website of the Pharmaceutical Benefits Management Institute, which provides selected details on services offered by its members. Online at http://www.pbmi.com/pbmdir.asp, accessed 1/26/05. Also see

reported that for 1995/1996, most PBMs offered their clients a comprehensive set of services, of which mail order ranked in the top three in terms of prevalence.

Table 1

PBM Ownership Type 1995/1996 [a]

Ownership Type [b]	Number of PBMs	Number of Covered Lives [c]	Percent of Covered Lives [d]
Retailer	23	27,534,000	7.6%
Pharmacy Benefit Managers	8	74,350,000	20.6%
Insurance	7	38,500,000	10.7%
Managed Care Organization	6	46,900,000	13.0%
Home Care	4	3,260,000	1.0%
Manufacturer	4	129,300,000	35.8%
Other	2	15,007,000	4.2%
Wholesaler	1	5,000,000	1.4%
Unknown	33	20,314,325	5.6%
Total	89	360,810,325	100.0%

(a) Per reporting in *Managed Healthcare* (MHC) or *Business Insurance* (BI)
(b) Retailer = pharmacy chain, other retailer or group of retailers; PBM = independent PBM; Insurance = indemnity insurance industry; Managed care organization = HMOs, PPOs and related health care organizations; Home Care = providers of home care services; Manufacturer = pharmaceutical manufacturer; Other includes Caremark (owned by a medical practice management and consulting company) and the Cystic Fibrosis Association; Wholesaler = drug wholesaler or wholesaler group
(c) Number of covered lives reported by PBMs in the category
(d) Percent based on total number of covered lives reported by all PBMs reporting in the MHC (1996) or BI (1995) directories
(e) Source of table: HCFA Master Contract HCFA-95-023/PK. "Assessment of the Impact of Pharmacy Benefit Managers", Wisconsin University – Madison. Center for Health Systems Research and Analysis; 30 September 1996. U.S. Department of Commerce National Technical Information Service. Table III.7, p. 32.

"Mail-order rates, capabilities foster increased competitiveness among PBMs", Drug Cost Management Report, September 12, 2003, online at http://www.findarticles.com/p/articles/mi_mONKV/is_11_4/ai_108118251 , accessed 1/25/2005.

132. While prescription volume dispensed through mail order was relatively low, and variable within the sample of PBMs, the trend towards utilization of this channel of distribution was already clearly increasing.[184]

B. 2. Implications of Diverse Ownership for Preserving "Secret" Information

133. An important implication of the patterns of diversified ownership and heterogeneous scale and scope of operations among PBMs is that commercial information regarding common negotiable contractual terms, such as rebates, discounts, audit rights, fee structures, penalties, risk assignment and other services offered is widely dispersed. This makes it difficult for any important information to remain uncovered on a sustained basis.

134. Commercial information concerning PBMs contracting and operations is known not only directly by those clients who contract with PBMs, but also by the diverse PBM owners – sometimes independent, but also commonly insurers, managed care organizations, retailers and wholesalers, as well as by the numerous health benefit consultant firms (e.g., Mercer, Segal, Towers Perrin, Wyatt, Hewitt Associates) who assist these various entities. While confidentiality commitments may make the terms of a specific contract "secret", general knowledge concerning what is negotiable and what is the range of terms typically offered is widespread. The presence of these various entities, each familiar with various aspects of PBM operations and finances, acts as a market discipline on the individual PBMs, even the larger ones.[185]

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[184] HCFA Master Contract [1996] *supra*, pp. 31-38.

[185] A 2003 Goldman Sachs industry analyst's report notes that consolidation among the Blue Cross – Blue Shield franchises not only has resulted in the Blues' captive PBM replacing a previously outsourced independent PBM (citing Anthem's acquisition of Trigot, which will be serviced beginning in 2004 by Anthem's internal PBM, a contract loss for Medco), but that managed care's internal PBMs are now also competing aggressively to provide PBM service to outside unaffiliated entities (citing PacifiCare Health Systems). See Goldman Sachs Global Equity Research, *Healthcare: Supply Chain -- Pharmacy Benefit Managers, United States*, October 16, 2003, pp. 12-13.

135. Nonetheless, the extent to which precise details concerning, for example, provisions of PBM rebate contracts with manufacturers, are publicly known is an important issue in this current litigation. I note in passing that this "lack of transparency" is common in other areas of the health care industries, such as managed care organization negotiated rates with hospitals, and those with general and specialty physician practices.[186] Lack of pricing transparency in prescription pharmaceuticals is also facilitated by the federally legislated prohibition of the reselling of any prescription drug that was previously purchased by a hospital or other "health care entity". This legislation thereby mitigates possible arbitrage operations that typically generate pricing information.[187] Outside of health care, there are other industries with legendary complex and seemingly non-transparent pricing, such as airlines. Thus it is useful to examine why and under what conditions lack of pricing transparency occurs. In the paragraphs that follow in this sub-section, I address this issue of price transparency involving PBMs.

136. First, it is useful to have a general idea of the relative importance of various revenue or "profit" sources for PBMs. A rough approximation to understanding the sources of PBMs "profits" can be obtained by examining industry analysts' reports. Recognizing the diversity among PBMs, along with numerous idiosyncratic accounting complexities, in 2002 one industry analyst estimated that for the PBM industry, the net revenue mix was as follows: Retail discounts accounted for 36% of net revenues, mail order retail margins 27%, manufacturer

[186] See, for example, David Dranove, M. Shanley and W. D. White, "How fast are hospital prices really rising?", *Medical Care*, 29(8), August 1991, pp. 690-696; Michael A. Morissey, "Do Hospitals and Physicians Charge Different Prices?", ch. 3 in Michael A. Morissey, *Cost Shifting in Health Care: Separating Evidence from Rhetoric*, Washington DC: The AEI Press, 1994; Alan Sorensen, "Insurer-Hospital Bargaining: Negotiated Discounts in Post-Deregulation Connecticut," *Journal of Industrial Economics*, Vol. 51 (2003) pp 469-490; Joseph P. Newhouse, *Pricing the Priceless: A Health Care Conundrum*, Cambridge, MA: MIT Press, 2002, especially ch. 3, "The Management of Moral Hazard and Stinting: Demand- and Supply-Side Prices,", pp. 79-103. Information issues are also discussed *in Improving Health Care: A Dose of Competition: A Report by the Federal Trade Commission and the Department of Justice*, July 2004, pp. 12-25.

[187] See the Prescription Drug Marketing Act of 1988, as described in the Department of Justice's Civil Resources Manual, available online at http://www.usdoj.gov/usao/eousa/foia_reading_room/usam/title4/civ00113.htm, last accessed 2/7/05.

rebates 22%, and administrative fees 15%.[188] The HCFA – University of Wisconsin 1996 study suggests two additional kinds of "rebates": revenues for sharing drug use information with manufacturers, and funds received by PBMs for projects sponsored by manufacturers.[189] The continued existence of these various revenue sources and the associated accounting complexities are corroborated by a recent New York Times report on employers uniting to curb prescription drug costs.[190] How the relative sizes of the PBM revenue sources are accounted for may depend on the way the revenue streams are structured, e.g., flat fee vs. a percentage of drug costs.

137. These various revenue sources suggests at least three sets of negotiated contracts involving PBMs:

(i) PBM with manufacturer regarding rebates, formulary details, information exchanges, auditing provisions, disease management services, other services;

(ii) PBM with retailers regarding the timing of and amounts reimbursed retailers for dispensing drugs (including for reimbursement of purchased ingredients, dispensing fees, other administrative fees), network services provided, drug utilization reviews, mail order provisions, professional performance measures and penalties; other terms (such as specialty pharmacy benefits) and claims processing details;

(iii) PBM with third party payor/insurer/employer regarding range of benefit plans offered, amounts received for managing beneficiaries' prescriptions dispensed at retail or mail order, copayment/ coinsurance arrangements, formulary development and management (particularly when the PBM client has a formulary differing from that of the PBM

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[188] Banc of America Securities, Equity Research United States, *Pharmacy Benefit Managers: Keeping a Lid o n Drug Costs*", Health Care Technology and Distribution Industry Overview, February 2002, Figure 13, p. 22. Details are not given on how this was calculated, and over what time period.

[189] HCFA Master Contract [1996] *supra*, p. xvii.

[190] See "Employers Unite in an Effort to Curb Prescription Costs" by Milt Freudenheim, *The New York Times*, February 3, 2005, p. C3.

national formulary), timing of and amounts reimbursed PBM for providing retail and mail order dispensing of drugs to member beneficiaries, claims processing details, rebate schedules and rebate management, audit rights, disease management, drug utilization review, and other terms, including specialty pharmacy.

Additional contracts may simultaneously involve payors/employers, PBMs, and retail/mail order pharmacies.[191] Notably, one set of contracts not included here is that between insurers and providers (such as physician practice networks), particularly for specialty pharmaceuticals. As I understand it, PBMs are typically not yet directly a part of that contract negotiating process, although the specialty pharmaceutical area is undergoing rapid changes. I will return to specialty pharmaceutical issues in Section V of this report. The other set of contracts not included here is that between generic drug manufacturers and retailers.

138. In the current litigation, particular attention has been focused on both the first set of contracts, that between manufacturers and PBMs, and the third set, that between PBMs and third party payors, in both cases involving rebates and their transparency. I begin with the first set of contracts involving rebates -- that between manufacturers and PBMs.

B. 3. Contracts Between PBMs and Drug Manufacturers: Rebate Transparency

139. The key issues addressed in PBM contracts with drug manufacturers are generally known; see, for example, Federal Trade Commission [1999].[192] The price and rebate provisions of these contracts typically use wholesale acquisition cost ("WAC") as a metric for determining

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[191] A May 2001 California HealthCare Foundation study, conducted by William M. Mercer, Inc. reports that in surveys with employers covering issues such as formulary rebates, research studies and clinical/health management issues, the researchers found that "Almost all employers we spoke with are reluctant to enter into direct contracts with pharmaceutical manufacturers because they believe that an objective third party is necessary to evaluate and manage these arrangements." See California HealthCare Foundation, *Prescription Drug Coverage and Formulary Use in California: Different Approaches and Emerging Trends*, prepared by William M. Mercer, Inc., May 2001, p. 47. This may be changing, however, as noted in the previous footnote.

[192] Roy Levy, *The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change*, Bureau of Economic Analysis, Federal Trade Commission, March 1999, Table III.1, p. 52.

the transaction prices for the prescription drugs subject to the contract. Incidentally, the FTC defines the WAC as follows:

> "WAC refers to the wholesale list price of the prescription drugs, and often differs from actual transaction prices. Transactions prices would equal WAC if no rebates, discounts or any other credits or allowances apply to transactions involving a particular prescription drug."[193]

140. It is useful to distinguish two situations involving branded, patent-protected drugs. First, for those drugs for which there is no other strong competitor in the same therapeutic class (e.g., Viagra, until about a year ago, for erectile dysfunction), typically manufacturers are unwilling to negotiate rebates. In such cases the drug has such a clear advantage over existing drugs for a condition that it quickly becomes the standard of care, to the relative exclusion of existing drugs. Anthony Barrueta, Senior Counsel for Kaiser Permanente, a large health maintenance organization, has noted in hearings before the DOJ/FTC that:

> "Under these circumstances, there is little opportunity for a purchaser to stimulate competition among manufacturers. Manufacturers are roughly free to set launch prices, they rarely discount those prices, and purchasers are price takers."[194]

Since rebates are rare in situations such as this, whether information about them is transparent is a moot point.

141. A very different situation emerges, however, when several patent-protected drugs compete with each other in the same therapeutic area (as is now the case for three erectile dysfunction drugs, Viagra, Cialis and Levitra). Kaiser's Senior Counsel Anthony Barrueta calls this the "competing monopoly/oligopoly" stage, and notes that this is where the possibility for price competition arises. He describes this environment as follows:

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[193] Levy, *supra*, p. 52, footnote 124.

[194] "Pharmacy Benefit Management Companies (PBMs)", comments of Anthony Barrueta, Senior Counsel, Kaiser Foundation Health Plan, Inc., Oakland, California, before the FTC/DOJ Joint Hearings, Health Care and Competition Law and Policy, June 26, 2003, p. 1; accessed online on December 31, 2004 at www.ftc.gov/ogc/healthcarehearings/docs/030626barrueta.pdf.

> "This stage represents the lion's share of the market at any given time. Here, there are multiple similar drugs on the market, all still under market exclusivity protection. Depending on how similar the drugs are – that is, how substitutable they are for each other – organized purchasers have the ability to either switch patients in a medically appropriate manner among the drugs (if the drugs are highly substitutable) or at least start new patients on a preferred drug (if the drugs are similarly effective, but switching would be disruptive to therapy). In either case, there is a competitive opportunity that can be taken advantage of. This is the area where formularies can be applied for the greatest effect on overall costs."[195]

142. It is important to note, I believe, that this "competing monopoly/oligopoly" situation is not an economics textbook example of a pure monopoly (for here there are several oligopolists competing, although each with market exclusivity due to patent protection), nor for certain is it an economics textbook example of perfect or pure competition among firms producing a homogeneous commodity, with free entry and exit of firms, and where buyers and sellers all have equal information regarding price. Instead, with competing monopolists/oligopolists, products are differentiated, and entry and exit are regulated by, among others, the FDA. It is precisely this market condition, however, that is most likely to give rise to rebates, and thus raise issue regarding the transparency of any rebates.

143. Industry analysts at Banc of America Securities describe the context and great importance of this stage, and the role played by PBMs, as follows:

> "On a regular basis (in our example, once per quarter) the PBM will remind all the branded pharmaceutical manufacturers (with which it has agreements) of their most recent contract to receive volume-based rebates (retroactive discounts). The PBM informs each manufacturer of the relevant volume figures and is in turn paid rebates. We note that these rebates, which we estimate average 10% of the cost of the drug, are paid only on branded, multisource pharmaceuticals (multisource refers to those pharmaceuticals that have competition in the marketplace – e.g. Claritin, Allegra and Zyrtec). Only 50% of all branded pharmaceuticals fall into this category; the rest are sole-source pharmaceuticals for which there is no competition (e.g., Viagra)."[196]

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[195] Anthony Barrueta, *supra*, pp. 1-2.

[196] Banc of America Securities, Equity Research United States, *Pharmacy Benefit Managers: Keeping a Lid o n Drug Costs*", Health Care Technology and Distribution Industry Overview, February 2002, p. 21. Note here the

144. In such a situation, if competition is to be effective, how transparent are results of price negotiations likely to become, and are consumers harmed or do they benefit when discounts or rebates are "secret"? Are consumers better or worse off if forced transparency of prices is mandated? What should one expect regarding the transparency of prices negotiated between PBMs and competing monopolists/oligopolists? I turn now to a discussion of the desirability of pricing transparency in the context of buyers (particularly organized buyers, such as health care organizations) attempting to create price competition among monopoly/oligopoly sellers offering differentiated products. I begin with insights from economic theory, cite some experimental evidence, recount testimony from a large buying group, as well as summarize recent position statements made by the FTC involving the desirability of forcing pricing transparency among PBMs.

B. 3. a Price Transparency with Competing Oligopolists/Monopolists: Theory

145. Within the area of applied microeconomics commonly known as industrial organization, there is a long oral tradition that in the context of oligopolists offering differentiated products, concludes, seemingly paradoxically, that "the best deal is a secret deal". This line of reasoning is frequently associated with two seminal papers by economics Nobel Laureate George Stigler.

146. First, in a 1961 article entitled "The Economics of Information", Stigler examined the costs and benefits of searching for information, such as that on product quality and price.[197] According to Stigler, purchasers will be willing to search for more information on price and

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usage of the term "multisource" which differs from the more common concept. Here "multisource" refers to various brands in the same therapeutic class, whereas multisource more commonly refers to both branded and generic versions of an identical molecular entity. Also, at the time this analysts' report was written, Viagra was the only member in the class of erectile dysfunction drugs. Since then, Cialis and Levitra have entered.

[197] George J. Stigler, "The Economics of Information", *Journal of Political Economy*, 69:3, June 1961, pp. 213-225.

quality as long as the expected incremental benefits from search exceeded expected incremental costs. Sellers understand this, and act appropriately. In the current context, when there is only one effective drug available in a therapeutic class, very little if any search or discounting will take place. When, however, several competing patent-protected drugs are available in a therapeutic class that under appropriate medical conditions can be substituted one for another, PBMs and third party payors face incentives to search for price discounts and rebates. In such a situation, will an oligopolist grant discounts, or will each steadfastly refuse to do so?

147. In a subsequent article entitled "A Theory of Oligopoly", published in 1964, Stigler examined the conditions under which an oligopolist would be willing to engage in discounting.[198] While explicit or even implicit collusion among oligopolistic sellers would be illegal, each manufacturer nonetheless would prefer that others not "cave in" to demands for discounts. As long as there is little possibility of being detected, however, it will typically be profitable for the manufacturer to grant a secret discount, particularly to a large buyer who can move market share. Detection of the discount becomes particularly difficult when it takes the indirect form of modifying some non-price dimension of the transaction. If manufacturers have reason to believe *ex ante*, however, that a potential purchaser is likely to report publicly and truthfully the "secret" prices tendered to it, the manufacturers are less likely to offer "secret" discounts in the first place.

148. Health economics textbook authors have considered implications of Stigler's notions of the economics of information for health care markets. Paul J. Feldstein, for example, in a section of his *Health Care Economics* textbook under the heading "Lack of Consumer Information" writes as follows:

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[198] George J. Stigler, "A Theory of Oligopoly", *Journal of Political Economy*, 72:1, February 1964, pp. 44-61.

> "It is important to keep in mind that since information is costly to gather, rational consumers are unlikely to become completely knowledgeable; they will gather information to the point where the marginal benefit of additional information equals the marginal cost of collecting it. For some types of medical services, the marginal benefit of additional information will be very high; for others, there will be little advantage to investing a great deal in the search process.
>
> Similarly, for price, product and quality competition to occur, it is not necessary that all consumers be informed. There are few, if any, markets where all purchasers are well informed. Lack of information by the majority of purchasers or even by the average purchaser does not preclude price competition from occurring. As long as the marginal purchaser is informed and price sensitive, demand curves have negative slopes, and providing competition for these purchasers is what makes competitive markets work."[199]

B. 3. b Price Transparency with Competing Oligopolists/Monopolists: Evidence

149. In terms of empirical support, Stigler [1964] provided only limited empirical evidence consistent with his theory of oligopoly pricing, namely, the less perfect the market knowledge (measured by the greater variance in transactions prices), the more extensive on average was the price-cutting off quoted or listed prices.

150. Because of the inherent difficulties in observing secret price dealing, it has proven difficult for researchers to obtain and report reliable and complete data on secret vs. non-secret discounts, along with their longer-term economic impacts on prices paid by consumers. There is, however, a small body of experimental research in economics that that provides evidence on secret discounting. Here a well-known study is that by Professors Douglas Davis and Charles Holt, who show that when transactions prices must be posted, potentially colluding firms in the laboratory maintained near-monopoly prices. However, when the possibility of offering secret discounts was introduced, laboratory sellers found sustaining implicit collusive agreements much

[199] Paul J. Feldstein, *Health Care Economics*, 4th Edition, Albany, New York: Delmar Publishers Inc., 1993, p. 327.

more difficult, and in such situations transactions prices tended to fall toward competitive levels, thereby benefiting consumers.[200]

151. Turning to the real world, rather than the worlds of economic theory, economics textbooks and experimental economics, I note that participants in and observers of the pharmaceutical marketplace have offered their own judgments on the applicability of the Stiglerian view that "the best deals are secret deals".

152. For example, Anthony Barrueta, Chief Counsel for Kaiser Foundation Health Plan, a staff model health maintenance organization, is quite clear concerning the desirability of confidential rather than transparent prices:

> "It is important and sensible that in their contractual relationships, PBMs and their employer/payer customers share adequate information to assure that the PBM is acting in the customer's best interest. However, in what is fundamentally an oligopoly prescription drug market, it is equally important to maximize market competition among drug manufacturers. We believe that price competition can best be achieved when negotiated prices and rebates are kept confidential. Widespread public disclosure of prices is unnecessary to assure that the ultimate payer receives most of the benefit of drug rebate agreements. Auditors operating under strict confidentiality agreements can assure that rebates are shared properly while maintaining confidentiality of prices. More expansive disclosure would ultimately result in fewer discounts and rebates, exacerbating the existing drug cost crisis."
>
> " We believe there is a significant risk that overregulation of PBMs, particularly in terms of indiscreet disclosure of negotiated discount and rebate arrangements, has the potential to undermine the ability of PBMs to be able to continue to negotiate prices effectively with manufacturers."[201]

153. Similar views appear in the Mathematica study prepared for the Henry J. Kaiser Family Foundation. Noting that rebates are highly confidential, particularly when they are steep, the Mathematica study authors stated:

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[200] Douglas D. Davis and Charles A. Holt, "Conspiracies and Secret Discounts in Laboratory Markets", *The Economic Journal*, 108, May 1998, pp. 736-756.
[201] Baruetta, *supra*, pp. 2-3.

> "PBMs guard this information closely, as do manufacturers. Having the rebate levels revealed in the transaction price might discourage manufacturers from offering steep discounts."[202]

154. That requiring prices to be fully transparent may in some cases hinder rather than foster price competition has been noted by the Federal Trade Commission in other contexts. For example, appearing in 1996 before the Commonwealth of Massachusetts Alcoholic Beverages Control Commission, Phoebe Morse, Director of the Boston Regional Office of the Federal Trade Commission, urged repeal of price posting regulations that require wholesalers of alcoholic beverages to post prices on a monthly basis and to adhere to those posted prices in their sales to retailers the following month. Stating that "We believe that repeal of the price posting regulations would increase competition", the FTC Regional Director went on to cite Stigler's 1964 Theory of Oligopoly article explicitly, and relate its conclusion of anticompetitive price transparency to the repeal of required price posting: "The availability of comprehensive price information tends to make it easier for industry members to coordinate prices tacitly and to detect and discourage deviation from the consensus price."[203] A footnote at the end of this quotation provided additional explanation, implicitly contrasting the retail brand licquor market setting with the "fully competitive" market paradigm:

> "In fully competitive markets, the provision of quick, accurate information generally tends to be pro-competitive. Indeed, perfect information is one of the underlying assumptions of the competitive model. But certain markets may not fit the competitive model well even in the absence of price regulation or price posting. They may be conducive to collusion because concentration is high in some segments or because entry is restricted by statute. In such markets, greater information can lead to the results described in the text."[204]

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[202] Henry J. Kaiser Family Foundation, *The Role of PBMs in Managing Drug Costs: Implications for a Medicare Drug Benefit*, Prepared by Mathematica Policy Research, Inc., January 2000, p. 50. Available online at www.pharmacy.ca.gov/publications/pbm_kff_role.pdf, last accessed 1/28/05.

[203] Statement of Phoebe Morse, Director, Boston Regional Office, Federal Trade Commission, to the Commonwealth of Massachusetts, Alcoholic Beverages Control Commission, June 26, 1996, pp. 1, 3. Available online at http://www.ftc.gov/os/1996/06/morse_st.pdf, last accessed January 27, 2005.

[204] Statement of Phoebe Morse [1996], *supra*, p. 3, fn. 6.

155. Many industrial organization economists are sympathetic with the view that in the context of competing oligopolists/monopolists, extensive price transparency is not necessarily beneficial because "the best deal is likely a secret deal". That view, however, is not universally shared, as the current litigation has demonstrated. Supporting arguments of the "beneficial price transparency" view, however, often implicitly invoke the full competition paradigm, which in my assessment is inappropriate as a characterization of transactions involving PBMs and manufacturers of branded single-source drugs. Attorney David Balto, for example, testifying at the same FTC hearings as Mr. Baruetta, argued that greater price transparency involving PBM rebates would assure competition by giving consumers bargaining power, "decrease prices by requiring PBMs to disclose price concessions and rebates from pharmaceutical manufacturers", so that "armed with information about rebates, buyers can encourage PBMs to compete to secure lower prices".[205] In a subsequent publication, Balto argued that before Congress extends the use of PBMs in a Medicare pharmaceutical benefit, "it must reform PBM markets to provide substantially greater transparency".[206]

B. 4. Contracts Between PBMs and Health Plans/Insurers: Rebate Transparency

156. Earlier I noted that it was useful to distinguish three sets of contracts that dealt with PBM transparency issues. To this point the discussion has centered on contracts between manufacturers and PBMs. A different set of contracts is that between PBMs and third party payors such as health plans and insurers, in which issues of disclosure of the manufacturer-PBM contract terms (the first set of contracts) can become an issue.

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[205] David A. Balto, "Pharmaceutical Benefit Managers: Competition and Transparency", FTC Healthcare Hearings, 6/26/03, accessed at www.ftc.gov/ogc/healthcarehearings/docs/030626balto.pdf. According to Plaintiffs' Expert Dr. Raymond S. Hartman, David A. Balto is the former Policy Director of the Bureau of Competition of the Federal Trade Commission. See *Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification*, supra, December 16, 2004, p. 73.

[206] David A. Balto, "Competitive Concerns and Price Transparency in the PBM Market", Update, Food and Drug Law Institute, September/October 2003, Powerpoint presentation, slide #11. Online at www.rkmc.com/pdf/price_transparency.pdf.

157. To a considerable extent, the degree of transparency between an individual PBM and a third party payer regarding rebates, as well as the extent to which they are passed through to the third party payors, is negotiable, as are audit rights. Examples of publicly available information regarding aspects of rebate transparency come from a variety of sources.

158. Banc of America industry analysts, for example, described the process in 2002 as follows:

> "A large percentage of the manufacturer rebates (we estimate an average of 70%) is passed on to the PBM client (the payor). This percentage varies a great deal, ranging from 0% to 100%, depending on the other components of the contract between the PBM and client. In other words, the PBM will get paid a fair amount for its services, one way or another – some clients would rather receive 100% of the rebate and pay higher administrative fees and/or get a lower share of pharmacy discounts, while others receive none of the rebates but pay much lower administrative fees and/or get a much higher share of pharmacy discounts".[207]

159. One reason health plans/insurers differ in their intensity to desire rebates vs. pharmacy discounts when negotiating with PBMs stems from the fact that if rebates are to be shared, the sizes of rebates are unknown *ex ante*, but are instead only revealed *ex post* after the health plans/insurers actual adjudicated volume claims and shares are calculated to assess whether targets had been attained, triggering the rebates. To the extent health plans/insurers differ in their willingness to take on risk, they will likely vary in their preference between unknown rebate amounts and more predictable discounts, with the more risk averse plans/insurers preferring the less risky discounts off AWP instead of uncertain rebate amounts.

160. Further discussion and information concerning rebates, audit rights, the bidding process and other subjects typically addressed when negotiating contracts between payors and PBMs, was presented at FTC public hearings in June 2003, and is also outlined in the joint

[207] Banc of America Securities, Equity Research United States, *Pharmacy Benefit Managers: Keeping a Lid o n Drug Costs*", Health Care Technology and Distribution Industry Overview, February 2002, p. 21.

FTC/DOJ report issued in 2004.[208] An earlier 2000 Report to the President by the Department of Health & Human Services stated that:

> "Industry sources report that the insurer or employer typically receives 70 to 90 percent of the rebates. In addition, the PBM will often guarantee a minimum per-prescription rebate, in case actual rebates received from manufacturers are lower than expected. While estimates differ, industry experts report that the value of rebates passed on to insurers or employers may average about $1.00 per claim."[209]

161. In discussing third party payor PBM benefit portfolio choices that were increasing in number and complexity, benefit consultants such as Pam Bertranb from Towers Perrin wrote already back in 1994, advising that "Clients should want to see the whole pool of rebate money and take a negotiated rate out of that, or ask for a higher guarantee".[210] Writing several years later in a different trade journal, health plan consultants John Tripodi and Paul McDonough of Health Information Systems, Inc., exhorted third party payors to conduct audits, stating:

> "One way to reduce risk is for an HMO, employer or indemnity payer to conduct an audit of their PBM. Although this may seem like a logical business procedure, in fact, audits have only recently become popular as payers seek new ways to control costs .A PBM audit may not happen without resistance, and there are several issues that a plan will need to address. First is the question of whether the plan has the legal right to perform an audit. Even if the current contract does not include audit rights, a PBM may cooperate to maintain positive relations for contract renewal. In the event that audit rights are not in the current contract and the PBM is not receptive, the plan should negotiate their inclusion in all future contracts."[211]

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[208] See, for example, the powerpoint presentation of John Richardson, The Health Strategies Consultancy, LLC, "PBMs: The Basics and an Industry Overview", particularly slide #25, "Manufacturer Rebates". Online at www.ftc.gov/ogc/healthcarehearings/docs/030626richardson.pdf , accessed 12/31/04; also see *Improving Health Care: A Dose of Competition, A Report by the Federal Trade Commission and the Department of Justice*, July 2004, ch. 7, "Industry Snapshot and Competition Law: Pharmaceuticals", pp. 15-18

[209] Report to the President: Prescription Drug Coverage, Spending, Utilization, and Prices, Department of Health and Human Services, April 2000, pp. 105-106.

[210] Quoted by Jeannie Mandelker, "Get The Most Out of Your PBM", *Business and Health*, November 1994, p. 40.

[211] John Tripodi and Paul McDonough, "Auditing Your PBM", *Prescription Price Watch*, March 1997, pp. 1,4.

Detailed discussions and advice concerning when to conduct a PBM audit, how to plan for it, and how to carry it out, including rebate audits, have long been easily found in widely available industry trade publications.[212]

162. Two other FTC-related matters regarding PBM price transparency merit brief discussion. First, after conducting public hearings and considering evidence brought to its attention, as well as information gained from various investigations, the FTC has taken a strong position believing that competition among PBMs is sufficient to ensure that decision-makers have sufficient information at their disposal to make wise choices that can benefit consumers. Notably, the FTC envisages a market-generated *optimal* amount of transparency as being the goal of policy, rather than a regulatory-imposed amount of transparency:

> "Vigorous competition in the marketplace for PBMs is more likely to arrive at an optimal level of transparency than regulation of those terms. Vigorous competition is also more likely to help ensure that gains from cost savings are passed on to consumers of health care services, either as lower premiums for health insurance, lower out-of-pocket costs (for that portion of health care expenditures borne directly by consumers through deductibles and co-payments), or improved services. Negotiated limitations on transparency are unlikely to be so severe that health plan sponsors cannot assess the price and quality of the services they are receiving. Just as competitive forces encourage PBMs to offer their best price and service combination to health plan sponsors to gain access to subscribers, competition also encourages disclosure of the information health plan sponsors require to decide on the PBM with which to contract."[213]

163. In related state (rather than federal) legislative proposals entailing increased risk of public disclosure of detailed PBM-manufacturer rebate provisions by third party payors, the

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[212] See, for example, Susan Peard and Kevin Johnson, "Taking stock of your PBM", *Business & Health*, March 2000, pp. 43-47.

[213] *Improving Health Care: A Dose of Competition, A Report by the Federal Trade Commission and the Department of Justice,* July 2004, ch. 7, "Industry Snapshot and Competition Law: Pharmaceuticals", p. 17.

FTC has reinforced the conclusion that mandated increased cost transparency is likely to increase rather than decrease consumers' prices.[214]

164. Other governmental agencies have agreed with the FTC on this issue. For example, in the process of estimating the likely costs of a Medicare Part D drug benefit for the elderly under proposed provisional amendments significantly increasing the risk of public disclosure of manufacturer-PBM pricing details, the Congressional Budget Office concluded:

> "Consequently, PBMs operating as part of the Medicare prescription drug plan would find it more difficult to obtain significant price concessions and rebates from drug manufacturers, who would be concerned that the terms of those favorable deals could be determined by competitors or other purchasers. Consequently, CBO estimates that, with this amendment, the degree of drug-cost management under S. 1 would decline and would no longer exceed the levels of cost management seen in the current employer market As a result, CBO estimates that section 133 would increase the estimated costs of S. 1 over the 2004-2013 period by $40 billion."[215]

165. Finally, in part because the PBM industry was already quite highly concentrated prior to the proposed acquisition of Advance PCS by Caremark in September 2003, the FTC undertook an investigation assessing likely competitive impacts of this merger between two of the largest PBMs, thereby placing the PBM industry again under close regulatory scrutiny.[216] In announcing that it was closing its investigation of the proposed acquisition and allowing the

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[214] See, for example FTC press release, "FTC Staff: California Bill May Raise Prices for Pharmaceuticals", online at http://www.ftc.gov/opa/2004/09/capbm.htm, accessed 1/15/2005; FTC press release, "FTC Staff: Rhode Island Bills Would Raise Prices for Pharmaceuticals", online at http://www.ftc.gov/opa/2004/04/ribills.htm, accessed 1/16/2005. In both cases, texts of the full letters can be obtained via the FTC website.

[215] Congressional Budget Office Cost Estimate, H.R. 1, Medicare Prescription Drug and Modernization Act of 2003, as passed by the House of Representatives on June 27, 2003, and S. 1, Prescription Drug and Medicare Improvement Act of 2003, as passed by the Senate on June 27, 2003, with a modification requested by Senate conferees, July 22, 2003, pp. 10-11. Online at http://www.cbo.gov/showdoc.cfm?index=4468&sequence=0, last accessed 1/26/05.

[216] Noting that the DOJ's horizontal merger guidelines classified a market as "highly concentrated" if its Herfindahl-Hirschman Index ("HHI") has a value of 1800, and as possibly raising DOJ/FTC concerns if the merger increases the HHI by more than 100 points, Goldman Sachs industry analysts reported that the pre-merger HHI was 2132 if the market were defined to include the various "captive" PBMs as a single firm, and 2708 if the market definition excluded captive PBMs entirely. Post-merger, the HHIs would increase by 243 and 345 points, respectively, to 3093 (excluding captive PBMs) and 3275 (including captive PBMs as a single PBM). See Goldman Sachs Global Equity Research, *Healthcare: Supply Chain – Pharmacy Benefit Managers, United States,* October 16, 2003, pp. 56-57.

Caremark/AdvancePCS acquisition to proceed,[217] the FTC noted that small employers would continue to be provided services by small, often regionally-oriented PBMs, post-acquisition, and that:

> " large employers are not likely to encounter anticompetitive effects from the acquisition in light of the competition that will exist following this transaction. Competition from the remaining independent, full-service PBMs with national scope – Medco, Express Scripts and the merged Caremark/AdvancePCS – and significant additional competition from several health plans and several retail pharmacy chains offering PBM services should suffice to prevent this acquisition from giving rise to a potentially anticompetitive price increase .
>
> At most, the acquisition is likely to increase the bargaining power of the merged PBM and to increase its shares (and correspondingly reduce the pharmacies' shares) of the gains flowing from contracts between the PBM and the pharmacies. It is likely that some of the PBM's increased shares would be passed through to PBM clients. Although retail pharmacies might be concerned about this outcome, a reduction in dispensing fees following the merger could benefit consumers."[218]

A footnote to this last paragraph added: "We anticipate that competition among PBMs will remain vigorous in the wake of the Caremark/AdvancePCS acquisition, and that this competition is likely to cause PBMs to pass on at least some of their cost savings to their customers in order to gain or retain their business."[219] Of particular note here is that in the first paragraph of the above quotation from the FTC, the FTC appears to acknowledge the competitive benefits and information flow aspects deriving from the highly diversified ownership of PBMs.

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[217] The Goldman Sachs industry observers compared this acquisition and its effects on competition to that of two large wholesalers, whose merger was also investigated and approved by the FTC. See Goldman Sachs Global Equity Research, *Healthcare: Supply Chain – Pharmacy Benefit Managers, United States,* October 16, 2003, pp. 56-57. Concentration and industry structure of the pharmaceutical wholesaler markets is discussed in Stephen W. Schondelmeyer and Marian V. Wrobel, *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices*, Introduction Final Report, Contract #500-00-0049, Task Order 1, Cambridge MA: Abt Associates, Inc., August 30, 2004, pp. 10-11.

[218] Statement of the Federal Trade Commission, In the Matter of Caremark Rx, Inc./AdvancePCS, File No. 031 0239, pp. 2-3, February 11, 2004. Online at www.ftc.gov/os/caselist/0310239/040211ftcstatement0310239.pdf, last accessed 01/16/05.

[219] Footnote 6, Statement of the Federal Trade Commission, In the Matter of Caremark Rx, Inc./Advance PCS, *supra*, p. 3.

166. In summary, because a very substantial proportion of transactions between manufacturers and PBMs involves patent-protected drugs competing with one another (in the "competing monopoly/oligopoly stage"), discounts and rebates from manufacturers to PBMs are likely to occur only if these price concessions are reasonably confidential, and even when verified by negotiated audits, are unlikely to be made public. There is a long tradition in economics suggesting that in such environments, "the best deals are secret deals". Third party payors have argued against increased price and rebate transparency. The FTC and DOJ have examined price and rebate transparency issues at considerable length, and have concluded that the structure of the PBM industry, and in particular its diverse ownership, facilitates vigorous competition. Indeed, within the last year the FTC has approved an acquisition involving two of the largest PBMs, noting that even after this acquisition, it expected competition to be vigorous, and rebates to be shared with third party payors.

C. Information with Vertically Integrated Mail Order Firms and PBMs

167. In sub-section A of Section III I examined information issues involving vertical integration between drug manufacturers and PBMs, while in the previous sub-section B I examined information issues and competition among various PBMs, including issues of rebate transparency and horizontal integration, both in the context of branded self-administered drugs. I now examine brand-generic issues raised by Plaintiffs regarding vertically integrated mail order firms and PBMs.

168. An issue that has figured quite prominently in debates leading up to passage of the Medicare Modernization Act of 2003, and more recently in various state legislatures, is the extent to which PBMs owning mail order services switch prescriptions from generics to brands, thereby perhaps increasing their rebates even as they secretly passed on to their insurer/third

party payor clients the higher costs of the branded drugs. This policy, dubbed "self-dealing", would not be sustainable if competition among PBMs were effective, for once discovered or suspected, PBM clients would shift to other PBMs that did not engage in such cost-increasing practices.[220] In the following paragraphs, I summarize and evaluate the available evidence addressing Plaintiffs' contention that self-dealing by vertically integrated mail order firms and PBMs has likely harmed the third party payor class. I also note forthcoming evidence on this issue that is scheduled for release by the FTC in June 2005.

169. Plaintiffs' Expert Dr. Raymond Hartman cites an "academic analysis" by Drs. James Langenfeld and Robert Maness finding "that the impact of competition among PBMs is insufficient to eliminate 'self-dealing' practices that increase the cost of pharmaceuticals."[221] I begin by summarizing and critiquing that apparently still unpublished study.

In the Executive Summary accompanying their report, Langenfeld and Maness state:

> "One way in which PBMs with captive mail order houses can increase sales of single source drugs is through therapeutic switching. Because it can take several days to fill a mail order prescription, mail order dispensing provides time for PBMs to obtain the necessary physician permission to switch prescriptions to single source alternatives. We find that such switching occurs more frequently in captive mail order houses than unaffiliated mail order houses, as evidenced by generic utilization being much less at captive mail order houses than at mail order houses that are unaffiliated with a PBM. Based on the best available evidence, captive mail order has a generic utilization of only 29.4 percent while independent mail order has a generic utilization rate of 38.9 percent."[222]

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[220] See *Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification*, September 3, 2004, supra, p. 15. Issues concerning the extent of competition in the PBM industry are addressed in the *Declaration of Steven J. Young in Opposition to the Plaintiff's Motion for Class Certification*, in the two pages prior to and then in Section C, Commercial Insurance Coverage and Reimbursement for Self-administered Brand Name Drugs, pp. 34 – 49. Dr. Hartman responds to Mr. Young in *Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification*, Section VI, pp. 72-82.

[221] Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification, September 3, 2004, *supra,* Attachment C, fn. 30, and other text on p. 10. The study cited is by James Langenfeld and Robert Maness, "The Cost of PBM 'Self-Dealing' Under a Medicare Prescription Drug Benefit", dated September 9, 2003. Langenfeld and Maness are both associated with LECG, a well-known economic consulting firm.

[222] Langenfeld and Maness [2003], *supra*, p. 1.

Note that the evidence Langenfeld-Maness cite as supporting their contention that therapeutic switching occurs is their finding here that generic utilization is much less at captive mail order houses than at mail order houses unaffiliated with a PBM. Based on this alleged generic utilization differential, they then estimate the cost impact of the alleged self-dealing involving therapeutic switching. It is useful to begin with some definitions.

170. The generic utilization rate is computed as the proportion of all prescription claims for all drugs – regardless of whether they have generic equivalents -- that are dispensed as generics. Another measure of substitution between generic and brand is based on just those molecules having both brand and generic versions available on the market, and that involves the calculation of the proportion of brand plus generic prescriptions for the identical molecule that are dispensed as generics; this is what industry observers frequently call the "generic substitution" rate, although Langenfeld and Maness and others have used the terms "generic utilization" and "generic substitution" rates interchangeably, along with the "generic dispensing" rate.[223] I note that in the above definition of generic substitution (i.e., the proportion of brand plus generic prescriptions for the identical molecule that are dispensed as generics), any "self-dealing" involving *between-molecule* therapeutic switching would not be captured.

171. Although details on their data sources are sketchy, Langenfeld and Maness apparently use aggregate mail order data as their measure of captive retail, stating "The best available proxy for captive retail is the figure for all mail order, since 77% of mail order sales are made from captive mail order divisions."[224] Regarding the source of data for unaffiliated mail

[223] See, for example, Langenfeld and Maness [2003], *supra*, p. 1 ("generic utilization rate"), p. 6 ("generic substitution rate") and p. 7, Figure 1 ("generic dispensing rate").
[224] Langenfeld and Maness [2003], *supra*, p. 6.

order, the only information that is given is a note to Figure 1, "Unaffiliated mail order estimates based on conversations with retail chains".[225]

172. Individuals receiving their drugs through mail order dispensing rather than from traditional retail pharmacies may differ significantly from one another, particularly in their utilization of long-term maintenance drugs treating chronic conditions (drugs more likely dispensed from mail order) versus drugs required for unexpected acute conditions and exacerbations (more likely dispensed from retail pharmacies on an as-needed basis). The generic share dispensed by retail pharmacies is also affected by the fact that among prescriptions dispensed for acute conditions at retail pharmacies, antibiotics are common, and an unusually large proportion of antibiotics are available in generic form.[226] This raises issues concerning how one should account for the differential mix of therapies treated by prescription drugs dispensed at retail vs. mail order pharmacies when comparing overall generic substitution rates.

173. Acknowledging that mail order prescriptions are particularly appealing for those individuals having long-term chronic conditions, Langenfeld and Maness attempt to control for such differential "mix" issues (apparently unsuccessfully, it turns out) by limiting their analysis to the ten therapeutic categories most dispensed through mail order within the ten largest cities. Data source details are again sketchy; a note to Figure 2, entitled simply "Various Generic Rates for Mail Order vs Retail: 2002 , states: "Source: Compiled by PRIME Institute, University of Minnesota from data provided by CVS Pharmacy based on IMS Health data for same mix of drugs drwn [sic] from 10 most frequently dispensed therapeutic categories of drugs in mail order

[225] Langenfeld and Maness [2003], *supra*, Note to Figure 1, p.7.
[226] *Takeda and Lilly Prescription Drug Benefit Cost and Plan Design Survey Report,* 2001 Edition, Tempe AZ: The Pharmacy Benefit Management Institute, Inc., p. 27.

pharmacy from August 2001 to July 2002 .[227] Hence, whether the data are just for CVS' sales or are national IMS Health data provided via CVS, is unclear; also unspecified is whether the averages are weighted or unweighted means. In any case, Langenfeld and Maness report their findings and their interpretation of them as follows:

> "The average generic substitution rate for mail order in these ten cities is 32.2 percent. The average retail generic substitution rate is 38%. Thus, the difference on average is 5.8%. This demonstrates that the mix is unlikely to account for the significant difference in substitution rates, and it is consistent with opportunistic self-dealing by PBMs dispensing drugs through their mail order divisions."[228]

174. When Langenfeld and Maness go a step further and exclude all single source drugs from the apparently same data set, thereby confining their analysis just to drugs that have multiple sources (brand and generic), they find that the average generic substitution rate for captive mail order in the ten cities is about 78%, slightly less than the 81% average for unaffiliated mail order (which they now call "non-captive mail order (as measured by its proxy)").[229] Although they report no statistical tests of significance, they conclude: "These data support the conclusion that differences in the mix do not explain the low level of generic utilization by PBM-owned mail order operations."[230]

175. Finally, based on "data from IMS Health for all products in a single category of drugs – cardiovascular products" (although whether this is just for CVS, or for a much larger retail sample, and whether for just ten cities or overall national retail, is unclear), Langenfeld and Maness report that the percentage of prescriptions "filled generically through mail order (the proxy for captive mail order)" was less than that for "retail (the proxy for independent mail

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[227] Langenfeld and Maness [2003], *supra*, Figure 2, p. 8. A footnote 16 on the same page adds: "The ten drug categories included in this analysis are adrenergic blockers, systemic antiarthritics (including NSAIDS), antidepressants, anti-ulcerants, calcium blockers, cholesterol reducers, oral diabetes products, non-injectable diuretics, renin angiotensin antagonists, and sex hormones."
[228] Langenfeld and Maness [2003], *supra*, p. 8.
[229] Langenfeld and Maness [2003], *supra*, p. 9.
[230] Langenfeld and Maness [2003], *supra*, p. 9.

order)": in 2001, the difference is 4.6 percentage points (34.6% for mail order vs. 39.2% for retail), while in 2002 the difference is 6.3% (36.0% for mail order vs. 42.3% for retail).[231]

176. In my judgment, the Langenfeld-Maness analysis is seriously deficient due to its lack of details concerning data sources, and its methodology that does not take into account sufficiently the implications of "mix" differentials between mail order and retail customer demand. While Plaintiffs' Expert Dr. Hartman characterizes it as an "academic analysis"[232], and although it is my understanding that over the years both Drs. Langenfeld and Maness have held adjunct academic appointments, to the best of my knowledge, the Langenfeld-Maness analysis has not been published in any peer-reviewed professional or academic journal, nor has it even been issued as an academic working paper, a traditional outlet for "academic analysis".[233] Perhaps it is for these reasons that in summarizing the Langenfeld-Maness findings, Dr. Hartman comments in the last line of a footnote that "It should be noted that these conclusions are subject to ongoing empirical analysis."[234]

177. Not surprisingly, the Pharmaceutical Care Management Association, a national trade association representing PBMs in the US, disagrees with the Langenfeld-Maness analysis

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[231] Langenfeld and Maness [2003], *supra*, Figure 4, p. 10, and text, p. 10.

[232] *Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification*, September 3, 2004, *supra*, Attachment C, p. 10, fn. 30.

[233] When the LECG website was visited to examine the professional biography of Dr. Robert S. Maness, his curriculum vita was found, apparently last revised 10/05/04, which reports employment at LECG, LLC, from June 1996 to the present, and Director, 2004 to the present. From 2000-2003, the curriculum vita reports that he was Adjunct Associate Professor at Texas A&M University, College Station, Texas. In the section of his curriculum vitae entitled "Papers and Publications" (p. 6), the following appears: "The Cost of PBM 'Self-Dealing' Under a Medicare Prescription Drug Benefit," with James Langenfeld, September 9, 2003." The LECG website also contains a biography of Dr. James A. Langenfeld, with the January 27, 2004 date on the last page (p. 11). The curriculum vita states that since August 1996 , he has been Director of LECG, LLC, and that from August 2002 to the present, he has been an Adjunct Professor at Loyola University Chicago, School of Law. In the section of his curriculum vita entitled "Papers and Publications", the following is listed as the second item: ""The Cost of PBM "Self-Dealing" Under a Medicare Prescription Drug Benefit", (with Robert Maness), September 2003." See www.lecg.com/website/lwbios.nsf/OpenPage/JamesLangenfeld/$FILE/Langenfeld.pdf, accessed January 24, 2005. Neither web search revealed distribution of this paper as an academic-issued working paper, nor as forthcoming in a peer-reviewed journal.

[234] *Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification*, September 3, 2004, *supra*, Attachment C, p. 9, fn. 24.

and its findings, claiming not only that it was "bankrolled by three of the nation's largest retail pharmacies", but also calling it "an eleventh-hour, rent-a-study, which directly contradicts independent government data".[235]

178. Recently, however, a peer-reviewed study has been published in a well-known health policy journal, *Health Affairs*, reporting findings that contradict those of Langenfeld and Maness concerning the interpretation of differential generic utilization rates by mail order vs. retail pharmacies.[236] The authors, Marta Wosinska and Robert S. Huckman, both on the faculty at Harvard Business School, begin by noting that use of the aggregate generic-dispensing rate (what Langenfeld and Maness also called the generic utilization rate) is problematic because it confounds brand-generic variation in the performance of the dispensing entities with variations in the composition of their clients demanding various prescription drugs (the "mix" issue).

179. To address issues of customer heterogeneity, Wosinska-Huckman utilize the universe of data from five large integrated PBMs having both retail and mail order pharmacy benefits, implying that the cohort of enrollees is the same when retail and mail order claims are compared.[237] In the retail sector, the top ten six-digit Generic Product Identifier classes

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[235] PCMA: Retail Pharmacy-Funded "Study" on PBMs Runs Afoul of Government Findings on PBM Cost-Savings, online at http://www.pcmanet.org/2004_addReleases/ReleasePrint/release40_print.html, accessed 1/22/2005. One "independent government data" study to which this press release apparently refers is that by the US General Accounting Office. While that study showed that prescription drugs (both branded and generic) received by beneficiaries through mail order pharmacies were on average less costly than those purchased by consumers paying cash at retail pharmacies, notably the study did not compare prices at captive mail order vs. unaffiliated mail order studies, as Langenfeld and Maness attempted to do. See *United States General Accounting Office, Federal Employees' Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies*, Report to the Honorable Byron L. Dorgan, U.S. Senate, GAO-03-196, January 2003. Available at www.gao.gov/cgi-bin/getrpt?GAO-03-196.

[236] Marta Wosinska and Robert S. Huckman, "Generic Dispensing And Substitution In Mail and Retail Pharmacies", *Health Affairs – Web Exclusive*, W4-409 to W4-416, posted 28 July 2004. Available online at www.healthaffairs.org. An abstract of the article was published in the hardcopy edition of *Health Affairs*, 23(5), September/October 2004, p. 284.

[237] The five PBMs are AdvancePCS, Caremark, Express Scripts, Medco and Prescription Services. The data exclude Medicaid and unfunded business, are national in scope, and cover the first six months of 2003. These data also include brand and generic over-the-counter medications that are covered by several plans, which I understand are not at issue in this litigation. See Wosinska and Huckman [2004], *supra*, pp. W4-410 and W4-411, and fn. 6 on p. W4-416.

accounted for 28.34% of claims, but in the mail order sector they accounted for a larger 40.89% of claims, implying that the therapeutic mix of drugs is more concentrated in mail order than in retail, or alternatively, that the drugs dispensed in retail come from more diverse therapeutic classes than those dispensed via mail order. Over all drug categories, when computing an aggregate generic dispensing rate (the proportion of all prescription claims filled by generic drugs, including molecules for which no generic was on the market), Wosinska-Huckman report a 48.51% share for retail and a 38.79% proportion for mail order, implying a differential of 9.72%, very close to the 9.5% differential reported by Langenfeld-Maness; however, these Wosinska-Huckman percentage *levels* of generic dispensing rates are about ten percentage points higher than those in Langenfeld-Maness, both for what the latter reported for unaffiliated mail order (38.9%) and for captive mail order (29.4%).[238]

180. To control for differences across therapeutic areas, Wosinska-Huckman first apply the same therapeutic mix to both retail and mail pharmacies (using mail six-digit weights in both the retail and mail channels, but employing channel-specific generic dispensing rates in each six-digit class), thereby creating what they called "normalized generic-dispensing rates". Using just this mix correction, Wosinska-Huckman reduced the aggregate generic dispensing rate differential of 9.72 points to 1.26 points (from 48.51% to 40.05% for retail, with mail unchanged at 38.79%), implying that "87 percent of the difference in the aggregate generic dispensing rates (more than 8.4 percentage points) can be explained by differences in therapeutic mix across channels."[239]

181. Next Wosinska-Huckman computed what they call the aggregate generic substitution rate, which for those molecules having both brand and generic versions, is the

[238] Wosinska-Huckman [2004], *supra*, Exhibit 4, p. W4-414; Langenfeld-Maness [2003], *supra*, Figure 1, p. 7. Recall my earlier comments on proxies used by Langenfeld-Maness for unaffiliated and captive mail order.
[239] Wosinska-Huckman [2004[, *supra*, p. W4-413, and Exhibit 4, p. W4-414.

proportion of claims dispensed as generics. In large part because of state mandatory substitution provisions, this aggregate generic substitution rate is very high for both channels – for mail order it is 92.99%, slightly greater (0.19 percentage points) than at retail where it is 92.80%.[240] Finally, when the authors normalize the aggregate generic substitution rate for the retail channel by using the mail channel mix of molecules, this difference increases slightly to 0.97 percentage points, 92.02% for retail (down from 92.80%), while mail remains the same at 92.99%.[241]

182. Wosinska-Huckman conclude by summarizing their most important finding and its implications:

> "The fact that mail order pharmacies have lower generic-dispensing rates than their retail counterparts has been used as evidence of self-dealing that could arise when a PBM is both a plan administrator and a pharmacy owner. Our analysis found that the difference in aggregate generic-dispensing rates between mail and retail pharmacies confounds variation in performance with differences in demand. Using the universe of claims for third party clients of five large PBMs, we found that 87 percent of the difference in the aggregate generic-dispensing rate is driven by differences in therapeutic mix . These results underscore the fact that it is impossible to make definitive judgments about pharmacy performance based on the generic-dispensing measure. As a result, addressing the proposed conflict of interest ultimately requires direct analysis of whether the monetary benefits from rebates outweigh the cost of interventions for therapeutic substitution and the obligations PBMs have to their clients."[242]

183. While the evidence presented in the peer-reviewed article by Wosinska-Huckman is in my judgment quite compelling, and not subject to some of the obvious problems in the unpublished paper by Langenfeld-Maness, a definitive conclusion concerning the extent of PBM self-dealing and its cost implications awaits the publication of others' research. For the moment,

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[240] Wosinska-Huckman attribute this unexpected finding, which runs contrary to the self-dealing conflict of interest argument, as reflecting the fact that although states' mandatory generic substitution provisions require the pharmacist to substitute the generic for brand unless the physician states "dispense as written", because mail order pharmacies typically have several days to fill a mail order prescription, they are more likely than is a retail pharmacist to call a physician who originally wrote "dispense as written" and obtain permission instead to substitute the generic for the brand. This difference, however, while unexpected, is relatively trivial. See Wosinska-Huckman [2004], *supra*, pp. W4-414 to W4-415.

[241] Wosinska-Huckman [2004], *supra*, p. W4-413 and Figure 4, p. W4-414.

[242] Wosinska-Huckman [2004], *supra*, pp. W4-415 to W4-416.

the most convincing evidence of which I am aware is that by Wosinska-Huckman, who report that once one accounts for differences in mix, generic dispensing and substitution rates are essentially the same at mail order vs. retail pharmacies.

184. Thus, Plaintiff's use of findings from an "academic study" regarding apparent differences in mail vs. retail generic substitution rates does not inform controversy in this litigation regarding the extent and cost implications of "conflict of interest" allegations regarding PBMs having integrated mail order operations.

185. Additional publicly available evidence on this "conflict of interest" issue will, however, soon emerge, and may be of assistance to the Court in the near future. A joint report recently issued by the Federal Trade Commission and the Department of Justice states that Section 110 of the Medicare Modernization Act of 2003 requires the Federal Trade Commission to conduct a "conflict of interest" study that includes the following:

> "1. An assessment of the differences in costs incurred by such enrollees and plans for prescription drugs dispensed by mail-order pharmacies owned by PBMs compared to mail-order pharmacies not owned by PBMs and community pharmacies.
> 2. Whether such group health plans are acting in a manner that maximizes competition and results in lower prescription drug prices for enrollees."[243]

The statute requires the FTC to report its findings and any necessary recommendations by June 2005.[244] Apparently stand-alone PBMs, health plan PBMs and retail pharmacy PBMs are providing data to the FTC.[245]

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[243] *Improving Health Care: A Dose of Competition*, Report by the Federal Trade Commission and the Department of Justice, July 2004, p. 18. Available from www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf
[244] Report by the Federal Trade Commission and the Department of Justice [2004], *supra*, p. 18.
[245] See Stephanie Kanwit, Special Counsel, PCMA, "Key Legal Challenges Facing PBMs", presentation given at the 2004 PCMA Annual Meeting, Phoenix, AZ, October 26, 2004. Online at http://pcmaevents.accrisoft.com/clientuploads/Annual_Meeting_2004/Files/KanwitAMMSSlidesfinal.ppt, accessed 1/22/05.

V. COMPETITION, INFORMATION, AND PRICE TRANSPARENCY: PHYSICIAN-ADMINISTERED DRUGS

186. The market environment in which PBMs have managed purchases of self-administered prescription drugs in the last two decades differs markedly from the distribution and management environment that has surrounded physician-administered drug purchases. I have outlined some of the most important differences in Subsection F of Section III of this report. These structural differences have significant implications for the quality of information flows and the nature of competition. A number of characteristics of the market environment for physician-administered drugs contribute to making it more vulnerable to mischief and abuse than is the market for self-administered drugs.

187. First, relative to the market for self-administered drugs, the dollar size of prescription-administered drug sales is very small, even after growing very rapidly in the last five years. In 2002, for example, it is estimated that Medicare paid $8.5 billion for physician-administered drugs, comprising about 3% of total Medicare spending.[246] Adding a 20% coinsurance amount paid by Medicare beneficiaries brings the total to about $10.6 billion.[247] Assuming that non-Medicare purchases of physician-administered drugs are as large as Medicare expenditures (a likely exaggerated assumption) brings the total to $21.2 billion. The entire U.S. prescription drug bill in 2002 was estimated to be about $194 billion.[248] Hence, expenditures on physician-prescribed drugs in 2002 were likely no more than 11% of the total prescription drug

[246] MedPAC [2003], *supra*, p. 154.
[247] One industry observer has estimated that "well over 95%" of beneficiaries receiving organ transplants have Medicare supplemental insurance, Medicaid, or another way to cover the program's 20% coinsurance for immunosuppressant medications. See "Specialty Pharmacies Struggle as Medicare Lowers Payment for Immunosuppressants", reprinted from the June 11, 2004 issue of *Drug Cost Management Report*. Available online at http://www.aishealth.com/DrugCosts/specialty/DCMRPharmaciesStruggleImmunosuppressants.html last accessed 12/29/2004.
[248] IMS Health, "U.S. Purchase Activity by Channel, 2002 , available online at http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_41551552_41633299,0o.html last accessed 10/25/04.

bill, and a smaller proportion in earlier years, given their substantial recent growth. Taking the total prescription drug market as being between 12% and 15% of overall national health expenditures suggests that in 2002, expenditures on physician-administered drugs were likely less than 1.5% of national health expenditures, and considerably smaller in earlier years. As I have discussed elsewhere,[249] and as stated earlier by the famous nineteenth century economist Alfred Marshall (and reinforced by Nobel Laureate George Stigler's economic theory of information[250]), there is a phenomenon called "the importance of being unimportant" which, in the current context, suggests that other things being equal, it may well be rational for budget managers to focus most of their attention on the larger budget items, and pay little heed to the smaller items. As a proportion of total spending, expenditures on physician-administered drugs have simply not been very important. That makes them more likely not to be on cost cutter's radar screens. As Plaintiff's Expert Dr. Raymond Hartman has stated:

> "While physician-administered drugs have become an increasingly large share of health plan spending in recent years, payers have only just begun to focus on cost control in this segment."[251]

With minimal vigilance, the possibility for unnoticed abuse and mischief is enhanced. Those able to make mischief understand the potential from benign neglect.

188. A second distinguishing feature of physician-administered drugs concerns their frequently being prescribed, purchased and dispensed by physicians, thereby becoming a source of their medical practice gross operating margin. Knowing this, managed care organizations that might otherwise expend considerable energies in seeking less costly sources of supplies for physician-administered drugs, such as via the buying power of specialty pharmacies, are less

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[249] Ernst R. Berndt, "The U.S. Pharmaceutical Industry: Why Major Growth In Times of Cost Containment?", *Health Affairs*, 20(2), March/April 2001, pp. 100-114.
[250] George J. Stigler, "The Economics of Information", *Journal of Political Economy*, 69:3, June 1961, pp. 213-225.
[251] *Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification*, September 3, 2004, p. D-10.

likely to invest in obtaining such information. Even if they do invest in such information gathering activities, if health plans shift to a third party supplier of the physician-administered drugs, they thereby might risk losing scarce specialty physicians from their physician network who have profited from the "spread". I alluded to this in Subsection F of Section III. Here I simply restate that the propensity for managed healthcare organizations to examine and monitor closely drug expenditures is understandably less in the case of physician-administered drugs relative to that for self-administered drugs.

189. In the context of this litigation, an example of the at best uneven flow of information involving physician-administered drugs is provided in the deposition of Paula Pfankuch, Senior Manager, Professional Reimbursement Programs, Blue Cross – Blue Shield of Illinois. Ms. Pfankuch implemented a policy of 150% of AWP reimbursement for non-chemotherapy drugs, but a 90% of AWP reimbursement for chemotherapy drugs. Apparently this differential physician reimbursement policy was implemented after the plan's Chief Medical Officer, Dr. Alan Korn, an oncologist, provided verbal information to Ms. Pfankuch that the 90% reimbursement was adequate for chemotherapy. According to Ms. Pfankuch, "Dr. Korn was an oncologist. He had a better feel for what it may cost an oncologist to acquire drugs."[252]

190. A third distinguishing feature of physician-administered drugs concerns their ambiguity in terms of whether they are paid for out of the medical vs. the prescription drug benefit. With self-administered drugs, this is not an issue, for these prescription drug expenditures are closely monitored in real time by PBMs employing impersonal and efficient information technology software. By contrast, the relatively small number of physician-

[252] Deposition of Paula Pfankuch, dated September 14, 2004, pp. 38-42, as cited in *Plaintiffs Appendix of Summary Charts in Support of Class Certification*, December 17, 2004, Appendix 1(b), pp. 21-22.